

**Notice of Allowability**

Application No.

10/565,987

Applicant(s)

LEE ET AL.

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_.
2. ☒ The allowed claim(s) is/are 1, 2, 15, 14, 16-18, 4, 7, 5, 6, 9, 3, 8 and 10-13 [renumbered as 1-18, respectively].
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.


**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in telephone interviews with Mr. Galgano on 9/18/2007 and 9/28/2007.

**Amendments to the Claims**

Claim 1. (Currently amended) A method for preparing a tamsulosin HCl sustained-release tablet, which comprises the steps of:

(A) dissolving tamsulosin HCl in a solvent and then dissolving a first hydroxypropylmethylcellulose phthalate in the tamsulosin HCl to prepare a binder solution;

(B) kneading the binder solution with an excipient mixture comprising a second hydroxypropylmethylcellulose phthalate and glyceryl dibehenate, and granulating the kneaded material to provide granules; and

(C) compressing the granules into a tablet;

wherein in step (A), the amount of the first hydroxypropylmethylcellulose phthalate is 10 to 150 parts by weight relative to 1 part by weight of tamsulosin HCl, and in step (B), the amount of the second hydroxypropylmethylcellulose phthalate in the excipient mixture is 50 to 500 parts by weight relative to 1 part by weight of tamsulosin HCl and the amount

of the glyceryl dibehenate in the excipient mixture is 10 to 200 parts by weight relative to 1 part by weight of tamsulosin HCl.

Claim 2. (Currently amended) The method of claim 1, which further comprises the step (B1) of drying and then sieving the granules, after the kneading and granulating step (B).

Claim 3. (Currently amended) The method of claim 2, which further comprises the additional excipient-adding step (B2) of adding at least one substance selected from the group consisting of a third hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose and corn starch, to the granules, after the kneading and granulating step (B) or the sieving step (B1).

Claim 7. (Currently amended) The method of claim 4, wherein the solvent is added at the amount of 180-300 parts by weight relative to one part by weight of tamsulosin HCl.

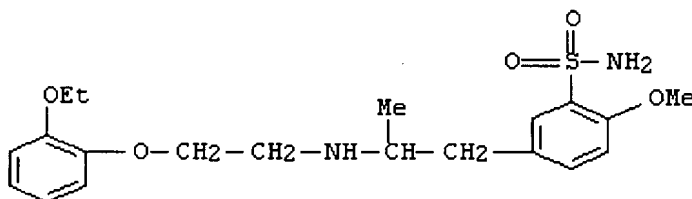
Claim 8. (Currently amended) The method of claim 3, wherein, at the excipient-adding step (B2), the third hydroxypropylmethylcellulose phthalate, if used, is added at the amount of 5-80 parts by weight relative to one part by weight of tamsulosin HCl, the hydroxypropylmethylcellulose, if used, is added at the amount of 10-300 parts by weight relative to one part by weight of tamsulosin HCl, and the corn starch, if used, is added at the amount of 10-300 parts by weight relative to one part by weight of tamsulosin HCl.

Claim 14. (Currently amended) The method of claim 15, wherein the solvent is added at the amount of 180-300 parts by weight relative to one part by weight of tamsulosin HCl.

**Amendments to the Specification**

Specification page 1, immediately below the Title, before paragraph 1 (and above "Technical Field"), insert the following application information --- This application is a 371 of PCT/KR04/01421, filed on June 15, 2004. ---

Specification page 2: delete the chemical formula at the top of page 2, and insert therefor the following corrected structure ---



• HCl

---

**Reasons for Allowance**

The following is an examiner's statement of reasons for allowance: The Examiner is in agreement with the International Search Report that there is no prior art reference that discloses, suggests or renders obvious the claimed invention, as presently

amended. Medline abstract 2007132208 is post-filing evidence that the selection and application of the claim-specified ingredients and proportions would not have been obvious. The abstract does not disclose glyceryl dibehenate and does disclose the presently claimed proportions. Moreover, applicant's specification provides the many advantages of the claimed invention (Test Examples 1-6 and Example 7 on pages 12-16), which establishes nonobviousness. For these reasons, the claimed invention as a whole is deemed to be allowable.

The references cited on the attached PTO-892 are cited to further show the state of the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Pak  
Primary Examiner  
Technology Center 1600